REMARKS

Applicant respectfully requests consideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 17-19, 27-29, 31, 32 and 34 are requested to be cancelled and claims 24-26 were previously canceled.

Claims 11, 13, 20, 21 and 30 are currently being amended to delete non-elected subject matter or to revise claim dependencies.

Claims 35-43 are added. Support for claims 35-38, 41 and 42 is found on page 8, lines 11-15 of the specification. Claims 39 and 43 have support in original claim 6 and in the specification on page 8, lines 19-22. Claim 40 has support in original claim 14 and in the specification on page 10, lines 14-15.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-16, 20-23, 30, 33 and 35-43 are now pending in this application.

In response to the Restriction Requirement, applicants elect claim 1-16, 21-23 in part and newly added claims 35 and 36 (Group I) with traverse.

The Examiner states that to have a general inventive concept under PCT Rule 13,1, the inventions need to be linked by a special technical feature. The Examiner has identified the special technical feature as a single-chain polypeptide comprising a binding site for CD19 and CD3. The Examiner interprets Jonge *et al.* ("Jonge") as disclosing a bispecific single chain polypeptide that binds CD19 and CD3, and therefore, he concludes that the technical feature recited in the claims is not a contribution over the prior art. The Examiner considers

that the groups set forth for restriction are not so linked as to form a single general concept under PCT Rule 13.1.

Applicants respectfully disagree with the Examiner's *a priori* anticipation rejection of the claims before an Office Action has been issued and also with the Examiner's interpretation of Jonge. Jonge merely discloses mouse-specific single-chain constructs.

In the present application, the specification as filed clearly and unambiguously teaches that the second domain of the inventive single-chain multi-functional polypeptide comprises a binding site of an immunoglobulin chain or an antibody specifically recognizing the CD3 antigen; see claim 1 as originally filed as well as page 2, 3rd paragraph. In the fourth paragraph (page 2, lines 25-28), the wording of originally filed claim 1 is further defined and specified. The person skilled in the art is taught that the binding site of the second domain "is directed against the CD3 antigen of human T cells". Of course, this further definition has to be read in conjunction with the main embodiment of the invention to which it directly refers. This being the case, it is further not possible to assign this further definition a deviating or contradictory interpretation as compared to the main embodiment. For this reason, the second domain, naturally, is not only directed against the CD3 antigen of human T cells, but, moreover, and in accordance with the broadest embodiment of the invention, specifically recognizes the human CD3 antigen.

Mutatis mutandis, it can be directly and unambiguously be derived from the present application as filed that a domain comprising a binding site which specifically recognizes the CD3 antigen is directed against the CD3 antigen of human T cells." In contrast, Jonge discloses mouse-specific single-chain constructs anti-mouse CD19 x anti-mouse CD3 (mCD19 x mCD3).

In contrast to the Examiner's interpretation of Jonge, the present invention provides for a single-chain multifunctional polypeptide as characterized in claim 1. Applicants submit that they have provided arguments against the use of Jonge as an anticipatory reference, and therefore, the groups of inventions are linked to form a single general inventive concept under PCT Rule 13.1.

Further, applicants wish to remind the Examiner that pursuant to MPEP § 1850, in PCT national phase cases, (§371 cases) the Examiner is required to follow the determination

of the International Bureau and cannot *sua sponte*, set forth his own groupings for purposes of examination. For example, *Caterpillar Tractor Co. v Commissioner of Patents*, 650 F.Supp. 218, 231 USPQ 590 (VA 1986).

The standards of restriction practice for PCT applications entering the national stage in the United States Patent & Trademark Office, as is the present application, are governed by 37 CFR §§ 1.475 and 1.499. The present application contains claims to three categories of product, process of use, and process of making, and pursuant to 37 CFR § 1.475 (b), an international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:...(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product;..." This category applies to the present application, and in view of this patent rule, it is requested that claims 20 and new dependent claims 37-40 (part of Group II) and claims 30 and 33 (Group V) and new dependent claims 41-43 directed to a method of treatment by the administration of the elected single-chain multi-functional antibody of the claims of Group I , and examined on the merits.

Applicants, of course, reserve the right to file one or more divisional applications covering the subject matter of the non-elected claims. Examination on the merits is kindly requested.

Respectfully submitted,

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